

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

MDL No. 2804

This document relates to:

THE MUSCOGEE (CREEK) NATION,
PLAINTIFF,

v.

PURDUE PHARMA L.P.; PURDUE PHARMA INC.;
THE PURDUE FREDERICK COMPANY; ENDO HEALTH
SOLUTIONS INC.; ENDO PHARMACEUTICALS INC.; ACTAVIS
LLC; ACTAVIS PHARMA, INC.; ALLERGAN FINANCE LLC;
WATSON LABORATORIES, INC.; TEVA PHARMACEUTICALS
USA, INC.; AMNEAL PHARMACEUTICALS, INC.; KVK-TECH,
INC.; MCKESSON CORPORATION; CARDINAL HEALTH, INC.;
CARDINAL HEALTH 110, LLC; AMERISOURCEBERGEN
CORPORATION; AMERISOURCEBERGEN DRUG
CORPORATION; MORRIS & DICKSON CO., LLC;
WALGREENS BOOTS ALLIANCE, INC.; WALGREEN CO.;
WAL-MART STORES, INC.; SAJ DISTRIBUTORS; GCP
PHARMA LLC; ANDA PHARMACEUTICALS, INC.; ANDA, INC.;
OMNICARE DISTRIBUTION CENTER LLC; SMITH DRUG
COMPANY; THE HARVARD DRUG GROUP, LLC; PHARMACY
BUYING ASSOCIATION; H.D. SMITH, LLC; CVS HEALTH
CORPORATION; CVS PHARMACY INC.; OKLAHOMA CVS
PHARMACY, LLC; THE DRUG WAREHOUSE; MAY'S DRUG
STORE; REASOR'S LLC; MED-X CORPORATION; ECONOMY
DISCOUNT PHARMACY; ECONOMY PHARMACY, INC.;
ECONOMY PHARMACY EXPRESS; CITY DRUG CO.; CITY
DRUG OF COWETA, INC.; SPOON DRUGS, INC.; CAREFIRST
PHARMACY, INC.; CITYPLEX PHARMACY; COUCH
PHARMACY ON SHERIDAN; ERNIE'S PHARMACY &
WELLNESS CENTER, INC.; FREELAND BROWN PHARMACY,
INC.; GADDY DISCOUNT DRUG, INC.; GETMANAPOTHECARY
SHOPPE, INC.; LANGSAM HEALTH SERVICES,
LLC; M & D STAR DRUG, INC.; MED-ECON DRUG, INC.;
OLYMPIA PHARMACY; PIPPENGER PHARMACIES LLC; AND
ROGERS DRUG CO. INC.,

DEFENDANTS.

Master Docket No.:
1:17-MD-02804-
DAP

Hon. Judge Dan
A. Polster

Case No.:
1:18-op-45459-
DAP

JURY TRIAL
DEMANDED

**H. D. SMITH, LLC'S ANSWER TO PLAINTIFF'S FIRST AMENDED COMPLAINT
AND AFFIRMATIVE DEFENSES**

Defendant H. D. Smith, LLC (“H. D. Smith”) now answers Plaintiff’s First Amended Complaint.

INTRODUCTION¹

1. H. D. Smith admits that prescription opioids are powerful pain-reducing medications and that “[w]hen used properly prescription opioids can help manage pain for certain patients.” H. D. Smith denies the allegation that “[e]ven then, these drugs can cause addiction, overdose, and death.” With respect to the remaining material allegations of Paragraph 1, H. D. Smith admits that when, prescription opioids are “used for non-medicinal purposes,” the risks of “addiction, overdose, and death” may be “amplified” to some unknown and unpleaded extent, but H. D. Smith denies any inference or implication that when prescription opioids are “used properly” “to treat chronic pain,” the risks of “addiction, overdose, and death” “are amplified.”

2. H. D. Smith denies the material allegations in Paragraph 2, except that it is admitted that the CDC published the referenced study, which is a writing that speaks for itself. Further answering, H. D. Smith lacks knowledge or information sufficient to form a belief as to the truth or falsity of any statements made in the referenced document.

3. Answering for itself only with respect to Paragraph 3, H. D. Smith denies the material allegations of Paragraph 3.

4. Paragraph 4 is not directed to H. D. Smith and no response from it is required.

5. Paragraph 5 is not directed to H. D. Smith and no response from it is required.

¹ H. D. Smith includes the headings from the First Amended Complaint only for ease and convenience of the Court and the parties. H. D. Smith neither admits nor endorses the content of any such heading.

6. H. D. Smith denies the material allegations of Paragraph 6, except it is admitted that the referenced documents are writings that speak for themselves. Further answering, H. D. Smith lacks knowledge or information sufficient to form a belief as to the truth or falsity of any statements made in the referenced documents.

7. H. D. Smith lacks knowledge or information sufficient to form a belief as to the truth or falsity of the material allegations of Paragraph 7.

8. H. D. Smith admits that diversion occurs whenever the supply chain of prescription opioids is broken and the drugs are transferred from a legitimate channel to an illegitimate one. With respect to the remaining allegations in Paragraph 8, H. D. Smith lacks knowledge or information sufficient to form a belief as to the truth or falsity of the material allegations of Paragraph 8.

9. H. D. Smith admits that the “legitimate supply chain for prescription opioids begins with the manufacture and packing of the pills. Manufacturers then transfer the pills to distribution companies.” H. D. Smith lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining material allegations of Paragraph 9.

10. H. D. Smith lacks knowledge or information sufficient to form a belief as to the truth or falsity of the material allegations of Paragraph 10.

11. With respect to the material allegations in Paragraph 11, H. D. Smith denies the allegation that “[a]t the distributor level, diversion occurs whenever distributors fill suspicious orders from retailers such as pharmacies.” H. D. Smith further denies the allegation that “suspicious orders include orders of an unusually large size, orders of a size that are disproportionately large in comparison to the population of a community served by a pharmacy, orders that deviate from a normal pattern, and orders of unusual frequency.” H. D. Smith admits

that diversion may occur “when distributors allow opioids to be lost or stolen from inventory or in transit,” but H. D. Smith denies any allegation, implication, or inference that in Oklahoma it ever “allow[ed] opioids to be lost or stolen from inventory or in transit.”

12. H. D. Smith lacks knowledge or information sufficient to form a belief as to the truth or falsity of the material allegations of Paragraph 12.

13. H. D. Smith denies the material allegations of Paragraph 13, except it is admitted that the referenced studies are writings that speak for themselves. Further answering, H. D. Smith lacks knowledge or information sufficient to form a belief as to the truth or falsity of any statements made in the referenced document.

14. With respect to the material allegations of Paragraph 14, H. D. Smith admits that “Diversion Manufacturer Defendants, Distributor Defendants and Pharmacy Defendants have legal obligations to combat diversion.” Answering for itself only, H. D. Smith denies the allegation that it “routinely and continuously violated these obligations, and have instead [has] taken advantage of the massively increased demand for prescription opioids for non-medicinal uses by profiting heavily from the sale of opioids that [it] knew, or should have known, were being diverted from the legitimate supply chain to illegitimate channels of distribution,” H. D. Smith denies the allegation that it “fail[ed] to comply with [its] legal obligations to prevent diversion and to alert authorities to potential diversion” and H. D. Smith denies the allegation that any such failure “continues today, despite (a) the well-known harm resulting from the opioid crisis, and (b) substantial fines regarding diversion levied against multiple of the Diversion Defendants.” Answering for itself only, H. D. Smith denies any allegation, inference, or implication that any “fines regarding diversion” have been levied against it.

15. Answering for itself only, with respect to the material allegations of Paragraph 15, H. D. Smith denies any allegation, inference, or implication that it engaged in any “misconduct” of any kind or “fail[ed] to comply with [its] legal obligations, [that] has led to an epidemic of prescription opioid abuse.” To the extent a further response is deemed necessary, H. D. Smith states that the documents referenced in Paragraph 15 speak for themselves, and that H. D. Smith lacks knowledge or information sufficient to form a belief as to the truth or falsity of any statements made in the referenced documents.

16. With respect to the material allegations of Paragraph 16, and answering only for itself, H. D. Smith denies any allegation, inference, or implication that it has engaged in any acts or omissions that have caused damage of any type or description to American Indians, including the Nation. H. D. Smith further states that the documents referenced in Paragraph 16 speak for themselves, and that H. D. Smith lacks knowledge or information sufficient to form a belief as to the truth or falsity of any statements made in the referenced documents.

17. With respect to the material allegations of Paragraph 17, and answering only for itself, H. D. Smith denies any allegation, inference, or implication that it has engaged in any acts or omissions that have caused damage of any type or description to American Indian youths. H. D. Smith further states that the documents referenced in Paragraph 17 speak for themselves, and that H. D. Smith lacks knowledge or information sufficient to form a belief as to the truth or falsity of any statements made in the referenced documents.

18. With respect to the material allegations of Paragraph 18, and answering only for itself, H. D. Smith denies any allegation, inference, or implication that it has engaged in any acts or omissions that have caused damage of any type or description to American Indian youths. H. D. Smith further states that the documents referenced in Paragraph 17 speak for themselves,

and that H. D. Smith lacks knowledge or information sufficient to form a belief as to the truth or falsity of any statements made in the referenced documents.

19. The allegations in Paragraph 19 contain no allegations directed against H. D. Smith and therefore, no response is required. To the extent a response is required, H. D. Smith states that the documents referenced in Paragraph 19 speak for themselves, and that H. D. Smith lacks knowledge or information sufficient to form a belief as to the truth or falsity of any statements made in the referenced documents.

20. With respect to the material allegations of Paragraph 20, and answering only for itself, H. D. Smith denies any allegation, inference, or implication that it has engaged in any acts or omissions that have caused damage of any type or description to the Nation's families. As to the remaining allegations in Paragraph 20, H. D. Smith lacks knowledge or information sufficient to form a belief as to the truth or falsity of the material allegations of Paragraph 20.

21. With respect to the material allegations of Paragraph 21, and answering only for itself, H. D. Smith denies any allegation, inference, or implication that it has engaged in any acts or omissions that have caused damage of any type or description to the Nation's families. As to the remaining allegations in Paragraph 21, H. D. Smith lacks knowledge or information sufficient to form a belief as to the truth or falsity of the material allegations of Paragraph 21.

22. With respect to the material allegations of Paragraph 22, and answering for itself only, H. D. Smith denies any allegation, inference, or implication that it has engaged in any acts or omissions that have caused damage of any type or description to the Nation. Further answering, H. D. Smith denies that the kinds of damages the Nation has alleged in Paragraph 22 are recoverable in this action.

23. With respect to the averments set forth in Paragraph 23, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, H. D. Smith denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation's damages.

24. With respect to the averments set forth in Paragraph 24, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, H. D. Smith denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation's damages.

PARTIES

I. PLAINTIFF

25. H. D. Smith lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 25.

26. H. D. Smith lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 26.

27. With respect to the averments set forth in Paragraph 27, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, H. D. Smith admits only that Kevin Dellinger is the Attorney General of the Nation, but denies that the Attorney General has standing to assert the claims made in the Complaint.

II. DEFENDANTS

A. Marketing Manufacturer Defendants

28. Paragraph 28 is not directed to H. D. Smith and no response from it is required.

29. Paragraph 29 is not directed to H. D. Smith and no response from it is required.

30. Paragraph 30 is not directed to H. D. Smith and no response from it is required.

31. Paragraph 31 is not directed to H. D. Smith and no response from it is required.

32. Paragraph 32 is not directed to H. D. Smith and no response from it is required.
33. Paragraph 33 is not directed to H. D. Smith and no response from it is required.
34. Paragraph 34 is not directed to H. D. Smith and no response from it is required.
35. Paragraph 35 is not directed to H. D. Smith and no response from it is required.
36. Paragraph 36 is not directed to H. D. Smith and no response from it is required.
37. Paragraph 37 is not directed to H. D. Smith and no response from it is required.
38. Paragraph 38 is not directed to H. D. Smith and no response from it is required.
39. Paragraph 39 is not directed to H. D. Smith and no response from it is required.
40. Paragraph 40 is not directed to H. D. Smith and no response from it is required.

B. Diversion Manufacturer Defendants

41. Paragraph 41 is not directed to H. D. Smith and no response from it is required.
42. Paragraph 42 is not directed to H. D. Smith and no response from it is required.
43. Paragraph 43 is not directed to H. D. Smith and no response from it is required.

C. Distributor Defendants

44. Paragraph 44 is not directed to H. D. Smith and no response from it is required.
45. Paragraph 45 is not directed to H. D. Smith and no response from it is required.
46. Paragraph 46 is not directed to H. D. Smith and no response from it is required.
47. Paragraph 47 is not directed to H. D. Smith and no response from it is required.
48. Paragraph 48 is not directed to H. D. Smith and no response from it is required.
49. Paragraph 49 is not directed to H. D. Smith and no response from it is required.
50. Paragraph 50 is not directed to H. D. Smith and no response from it is required.
51. Paragraph 51 is not directed to H. D. Smith and no response from it is required.
52. Paragraph 52 is not directed to H. D. Smith and no response from it is required.
53. Paragraph 53 is not directed to H. D. Smith and no response from it is required.

54. Paragraph 54 is not directed to H. D. Smith and no response from it is required.

55. Paragraph 55 is not directed to H. D. Smith and no response from it is required.

56. Paragraph 56 is not directed to H. D. Smith and no response from it is required.

57. Paragraph 57 is not directed to H. D. Smith and no response from it is required.

58. Paragraph 58 is not directed to H. D. Smith and no response from it is required.

59. Paragraph 59 is not directed to H. D. Smith and no response from it is required.

60. Paragraph 60 is not directed to H. D. Smith and no response from it is required.

61. H. D. Smith denies the material allegations of Paragraph 61, except that it is

admitted that H. D. Smith is a limited liability company organized and existing under the laws of the State of Delaware.

62. With respect to the material allegations of Paragraph 62, and answering only for itself, H. D. Smith denies any allegation, inference, or implications that it “consistently failed to comply with its legal obligations concerning prescription opioid diversion.” H. D. Smith lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 62.

D. Pharmacy Defendants

63. Paragraph 63 is not directed to H. D. Smith and no response from it is required.

64. Paragraph 64 is not directed to H. D. Smith and no response from it is required.

65. Paragraph 65 is not directed to H. D. Smith and no response from it is required.

66. Paragraph 66 is not directed to H. D. Smith and no response from it is required.

67. Paragraph 67 is not directed to H. D. Smith and no response from it is required.

68. Paragraph 68 is not directed to H. D. Smith and no response from it is required.

69. Paragraph 69 is not directed to H. D. Smith and no response from it is required.

70. Paragraph 70 is not directed to H. D. Smith and no response from it is required.

71. Paragraph 71 is not directed to H. D. Smith and no response from it is required.
72. Paragraph 72 is not directed to H. D. Smith and no response from it is required.
73. Paragraph 73 is not directed to H. D. Smith and no response from it is required.
74. Paragraph 74 is not directed to H. D. Smith and no response from it is required.
75. Paragraph 75 is not directed to H. D. Smith and no response from it is required.
76. Paragraph 76 is not directed to H. D. Smith and no response from it is required.
77. Paragraph 77 is not directed to H. D. Smith and no response from it is required.
78. Paragraph 78 is not directed to H. D. Smith and no response from it is required.
79. Paragraph 79 is not directed to H. D. Smith and no response from it is required.
80. Paragraph 80 is not directed to H. D. Smith and no response from it is required.
81. Paragraph 81 is not directed to H. D. Smith and no response from it is required.
82. Paragraph 82 is not directed to H. D. Smith and no response from it is required.
83. Paragraph 83 is not directed to H. D. Smith and no response from it is required.
84. Paragraph 84 is not directed to H. D. Smith and no response from it is required.
85. Paragraph 85 is not directed to H. D. Smith and no response from it is required.
86. Paragraph 86 is not directed to H. D. Smith and no response from it is required.
87. Paragraph 87 is not directed to H. D. Smith and no response from it is required.
88. Paragraph 88 is not directed to H. D. Smith and no response from it is required.
89. Paragraph 89 is not directed to H. D. Smith and no response from it is required.
90. Paragraph 90 is not directed to H. D. Smith and no response from it is required.
91. Paragraph 91 is not directed to H. D. Smith and no response from it is required.
92. Paragraph 92 is not directed to H. D. Smith and no response from it is required.

JURISDICTION AND VENUE

93. With respect to the averments set forth in Paragraph 93, those averments allege legal conclusions of law to which no response is required. To the extent a response is deemed necessary, H. D. Smith lacks knowledge or information sufficient to form a belief about the truth or falsity of the material allegations of Paragraph 93.

94. With respect to the averments set forth in Paragraph 94, those averments allege legal conclusions of law to which no response is required. To the extent a response is deemed necessary, H. D. Smith lacks knowledge or information sufficient to form a belief about the truth or falsity of the material allegations of Paragraph 94.

95. With respect to the averments set forth in Paragraph 95, those averments allege legal conclusions of law to which no response is required. To the extent a response is deemed necessary, H. D. Smith lacks knowledge or information sufficient to form a belief about the truth or falsity of the material allegations of Paragraph 95.

FACTUAL BACKGROUND

I. PRESCRIPTION OPIOIDS ARE HIGHLY DANGEROUS

96. H. D. Smith denies the material allegations of Paragraph 96, except it is admitted that the referenced document is a writing that speaks for itself. To the extent a response is deemed necessary, H. D. Smith admits only that it contains content referenced and that prescription opioids are powerful pain-reducing medications that include non-synthetic, partially-synthetic, and fully-synthetic derivatives of the opium poppy, and that while these drugs have benefits when used properly, they also pose serious risks.

97. With respect to the averments set forth in Paragraph 97, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, H. D. Smith admits the material allegations of Paragraph 97 but denies any allegation,

inference, or implication that it has engaged in any acts or omissions that have contributed to the Nation's opioid epidemic or any of the Nation's damages.

98. With respect to the averments set forth in Paragraph 98, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, H. D. Smith, answering for itself only, denies the material allegations directed at it in Paragraph 98.

II. MARKETING MANUFACTURER DEFENDANTS HAVE LEGAL DUTIES TO DISCLOSE ACCURATELY THE RISKS OF OPIOIDS

99. Paragraph 99 is not directed to H. D. Smith and no response from it is required.

100. Paragraph 100 is not directed to H. D. Smith and no response from it is required.

101. Paragraph 101 is not directed to H. D. Smith and no response from it is required.

III. MARKETING MANUFACTURER DEFENDANTS VIOLATED THEIR DUTIES

A. Marketing Manufacturer Defendants Made Misleading Statements About the Risks of Prescribing Opioids to Treat Chronic Pain and Failed to State Accurately the Magnitude of Those Risks

102. Paragraph 102 is not directed to H. D. Smith and no response from it is required.

103. Paragraph 103 is not directed to H. D. Smith and no response from it is required.

1. Marketing Manufacturer Defendants Misrepresented the Risks of Addiction to Prescription Opioids

104. Paragraph 104 is not directed to H. D. Smith and no response from it is required.

105. Paragraph 105 is not directed to H. D. Smith and no response from it is required.

106. Paragraph 106 is not directed to H. D. Smith and no response from it is required.

107. Paragraph 107 is not directed to H. D. Smith and no response from it is required.

108. Paragraph 108 is not directed to H. D. Smith and no response from it is required.

109. Paragraph 109 is not directed to H. D. Smith and no response from it is required.

110. Paragraph 110 is not directed to H. D. Smith and no response from it is required.

111. Paragraph 111 is not directed to H. D. Smith and no response from it is required.
112. Paragraph 112 is not directed to H. D. Smith and no response from it is required.
113. Paragraph 113 is not directed to H. D. Smith and no response from it is required.
114. Paragraph 114 is not directed to H. D. Smith and no response from it is required.
115. Paragraph 115 is not directed to H. D. Smith and no response from it is required.

2. Marketing Manufacturer Defendants Misleadingly Claimed that Patients Who Were Showing Signs of Addiction Were Not Actually Addicted

116. Paragraph 116 is not directed to H. D. Smith and no response from it is required.
117. Paragraph 117 is not directed to H. D. Smith and no response from it is required.
118. Paragraph 118 is not directed to H. D. Smith and no response from it is required.
119. Paragraph 119 is not directed to H. D. Smith and no response from it is required.

3. Marketing Manufacturer Defendants Falsely Claimed There Was No Risk in Increasing Opioid Dosages to Treat Chronic Pain

120. Paragraph 120 is not directed to H. D. Smith and no response from it is required.
121. Paragraph 121 is not directed to H. D. Smith and no response from it is required.
122. Paragraph 122 is not directed to H. D. Smith and no response from it is required.
123. Paragraph 123 is not directed to H. D. Smith and no response from it is required.
124. Paragraph 124 is not directed to H. D. Smith and no response from it is required.
125. Paragraph 125 is not directed to H. D. Smith and no response from it is required.

B. Marketing Manufacturer Defendants' Misleading Statements Were Designed for Maximum Effect and Targeted to Specific Audiences

126. Paragraph 126 is not directed to H. D. Smith and no response from it is required.
127. Paragraph 127 is not directed to H. D. Smith and no response from it is required.
128. Paragraph 128 is not directed to H. D. Smith and no response from it is required.
129. Paragraph 129 is not directed to H. D. Smith and no response from it is required.

130. Paragraph 130 is not directed to H. D. Smith and no response from it is required.
131. Paragraph 131 is not directed to H. D. Smith and no response from it is required.
132. Paragraph 132 is not directed to H. D. Smith and no response from it is required.
133. Paragraph 133 is not directed to H. D. Smith and no response from it is required.
134. Paragraph 134 is not directed to H. D. Smith and no response from it is required.
135. Paragraph 135 is not directed to H. D. Smith and no response from it is required.
136. Paragraph 136 is not directed to H. D. Smith and no response from it is required.
137. Paragraph 137 is not directed to H. D. Smith and no response from it is required.

C. Marketing Manufacturer Defendants Knew or Should Have Known That Their Statements Were Misleading

138. Paragraph 138 is not directed to H. D. Smith and no response from it is required.
139. Paragraph 139 is not directed to H. D. Smith and no response from it is required.
140. Paragraph 140 is not directed to H. D. Smith and no response from it is required.
141. Paragraph 141 is not directed to H. D. Smith and no response from it is required.
142. Paragraph 142 is not directed to H. D. Smith and no response from it is required.
143. Paragraph 143 is not directed to H. D. Smith and no response from it is required.
144. Paragraph 144 is not directed to H. D. Smith and no response from it is required.
145. Paragraph 145 is not directed to H. D. Smith and no response from it is required.
146. Paragraph 146 is not directed to H. D. Smith and no response from it is required.
147. Paragraph 147 is not directed to H. D. Smith and no response from it is required.
148. Paragraph 148 is not directed to H. D. Smith and no response from it is required.

D. Marketing Manufacturer Defendants' Conduct Violated Their Duties

149. Paragraph 149 is not directed to H. D. Smith and no response from it is required.
150. Paragraph 150 is not directed to H. D. Smith and no response from it is required.

151. Paragraph 151 is not directed to H. D. Smith and no response from it is required.

E. The Nation Was Harmed by Marketing Manufacturer Defendants' Name-Brand Prescription Opioids and Their Generic Equivalents as a Result of Defendants' Wrongful Marketing Conduct

152. Paragraph 152 is not directed to H. D. Smith and no response from it is required.

153. Paragraph 153 is not directed to H. D. Smith and no response from it is required.

154. Paragraph 154 is not directed to H. D. Smith and no response from it is required.

155. Paragraph 155 is not directed to H. D. Smith and no response from it is required.

156. Paragraph 156 is not directed to H. D. Smith and no response from it is required.

F. Generic Marketing Manufacturer Defendants Failed to Effectively Communicate with Physicians and Patients about Their Products

157. Paragraph 157 is not directed to H. D. Smith and no response from it is required.

158. Paragraph 158 is not directed to H. D. Smith and no response from it is required.

159. Paragraph 159 is not directed to H. D. Smith and no response from it is required.

160. Paragraph 160 is not directed to H. D. Smith and no response from it is required.

161. Paragraph 161 is not directed to H. D. Smith and no response from it is required.

IV. DIVERSION DEFENDANTS HAVE LEGAL DUTIES TO PREVENT OPIOID DIVERSION

162. With respect to the averments set forth in Paragraph 162, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, and answering for itself only, H. D. Smith denies any allegation, implication, or inference that any act or omission by it caused or contributed to the diversion of prescription opiates for nonmedical purposes in the Nation. Further answering, H. D. Smith denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation's damages.

163. With respect to the averments set forth in Paragraph 163, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, and answering for itself only, H. D. Smith denies that it violated any such duty; and H. D. Smith denies any allegation, implication, or inference that the sources of federal law create any private cause of action for any departure therefrom.

164. With respect to the averments set forth in Paragraph 164, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, and answering for itself only, H. D. Smith denies the material allegations of Paragraph 164.

165. With respect to the material allegations set forth in Paragraph 165, those allegations contain conclusions of law to which no response is required. To the extent a response is deemed necessary, and answering for itself only, H. D. Smith denies the material allegations of Paragraph 165.

A. Federal Law Sets a Standard of Care That Diversion Defendants Must Follow

1. Diversion Manufacturer Defendants' and Distributor Defendants' Standard of Care Under Federal Law

166. With respect to the material allegations set forth in Paragraph 166, those allegations contain conclusions of law to which no response is required. To the extent a response is deemed necessary, and answering for itself only, H. D. Smith denies any allegation, implication, or inference that it violated the FCSA or that it caused or contributed to any of the Nation's damages.

167. With respect to the averments set forth in Paragraph 167, those averments allege conclusions of law to which no response is required. To the extent a response is deemed

necessary, and answering for itself only, H. D. Smith denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation's damages.

168. With respect to the averments set forth in Paragraph 168, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, and answering for itself only, H. D. Smith denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation's damages.

169. With respect to the averments set forth in Paragraph 169, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, and answering for itself only, H. D. Smith denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation's damages.

2. Pharmacy Defendants' Standard of Care Under Federal Law

170. Paragraph 170 is not directed to H. D. Smith and no response from it is required.

171. Paragraph 171 is not directed to H. D. Smith and no response from it is required.

172. Paragraph 172 is not directed to H. D. Smith and no response from it is required.

173. Paragraph 173 is not directed to H. D. Smith and no response from it is required.

174. Paragraph 174 is not directed to H. D. Smith and no response from it is required.

175. Paragraph 175 is not directed to H. D. Smith and no response from it is required.

176. Paragraph 176 is not directed to H. D. Smith and no response from it is required.

177. Paragraph 177 is not directed to H. D. Smith and no response from it is required.

B. Oklahoma Law Sets a Standard of Care That Diversion Defendants Must Follow

1. Diversion Manufacturer Defendants' and Distributor Defendants' Standard of Care Under Oklahoma Law

178. With respect to the averments set forth in Paragraph 178, those averments allege conclusions of law to which no response is required. To the extent a response is deemed

necessary, H. D. Smith denies any allegation, implication, or inference that it violated the Oklahoma Uniform Controlled Substances Act, that it “failed to meet the relevant standard of conduct society expects from them”, or that any act or omission by it caused or contributed to any of the Nation’s damages.

179. With respect to the averments set forth in Paragraph 179, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, H. D. Smith denies any allegation, implication, or inference that it violated the Oklahoma Uniform Controlled Substances Act, or that any act or omission by it caused or contributed to any of the Nation’s damages.

180. With respect to the averments set forth in Paragraph 180, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, H. D. Smith denies any allegation, implication, or inference that it violated the Oklahoma Uniform Controlled Substances Act, or that any act or omission by it caused or contributed to any of the Nation’s damages.

181. With respect to the averments set forth in Paragraph 181, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, H. D. Smith denies any allegation, implication, or inference that it violated the Oklahoma Uniform Controlled Substances Act, or that any act or omission by it caused or contributed to any of the Nation’s damages.

182. With respect to the averments set forth in Paragraph 182, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, H. D. Smith denies any allegation, implication, or inference that it violated the

Oklahoma Uniform Controlled Substances Act, or that any act or omission by it caused or contributed to any of the Nation's damages.

183. With respect to the averments set forth in Paragraph 183, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, H. D. Smith denies any allegation, implication, or inference that it violated the Oklahoma administrative code, or that any act or omission by it caused or contributed to any of the Nation's damages.

184. With respect to the averments set forth in Paragraph 184, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, H. D. Smith denies any allegation, implication, or inference that it violated the Oklahoma administrative code, or that any act or omission by it caused or contributed to any of the Nation's damages.

185. With respect to the averments set forth in Paragraph 185, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, H. D. Smith denies any allegation, implication, or inference that it violated the Oklahoma Uniform Controlled Substances Act or administrative code, or that any act or omission by it caused or contributed to any of the Nation's damages.

2. Pharmacy Defendants' Standard of Care Under Oklahoma Law

186. Paragraph 186 is not directed to H. D. Smith and no response from it is required.
187. Paragraph 187 is not directed to H. D. Smith and no response from it is required.
188. Paragraph 188 is not directed to H. D. Smith and no response from it is required.
189. Paragraph 189 is not directed to H. D. Smith and no response from it is required.
190. Paragraph 190 is not directed to H. D. Smith and no response from it is required.
191. Paragraph 191 is not directed to H. D. Smith and no response from it is required.

192. Paragraph 192 is not directed to H. D. Smith and no response from it is required.
193. Paragraph 193 is not directed to H. D. Smith and no response from it is required.
194. Paragraph 194 is not directed to H. D. Smith and no response from it is required.
195. Paragraph 195 is not directed to H. D. Smith and no response from it is required.
196. Paragraph 196 is not directed to H. D. Smith and no response from it is required.
197. Paragraph 197 is not directed to H. D. Smith and no response from it is required.
198. Paragraph 198 is not directed to H. D. Smith and no response from it is required.
199. Paragraph 199 is not directed to H. D. Smith and no response from it is required.

V. DIVERSION DEFENDANTS HAVE FAILED TO FULFILL THEIR DUTIES

A. Diversion Manufacturer Defendants and Distributor Defendants Understood Their Duties and Violated Them Anyway

1. Diversion Manufacturer Defendants and Distributor Defendants Understood and Acknowledged Their Duties

200. Answering for itself only, H. D. Smith denies the material allegations in Paragraph 200.
201. Answering for itself only, H. D. Smith admits that the DEA has provided guidance to distributors on the requirements of suspicious order reporting, but denies that any such guidance provided complete, specific, or practical guidance to distributors with respect to the requirements of suspicious order reporting.

202. Answering for itself only, H. D. Smith admits that since 2006, “the DEA has briefed distributors regarding legal, regulatory, and due diligence responsibilities.” Further answering, H. D. Smith denies that any such DEA briefings provided meaningful and specific guidance relating to “red flags distributors should look for to identify potential diversion.”

203. Answering for itself only, H. D. Smith denies the material allegations of Paragraph 203, except it is admitted that the referenced documents speak for themselves, and that

H. D. Smith lacks knowledge or information sufficient to form a belief as to the truth or falsity of any statements made in the referenced documents.

204. H. D. Smith lacks knowledge or information sufficient to form a belief about the truth or falsity of the material allegations of Paragraph 204.

205. Answering for itself only, H. D. Smith denies the material allegation of Paragraph 205, except that it is admitted that the document referenced in Paragraph 205 speaks for itself, and that H. D. Smith lacks knowledge or information sufficient to form a belief as to the truth or falsity of any statements made in the referenced document.

206. Answering for itself only, H. D. Smith denies the material allegations in Paragraph 206, except it is admitted that the referenced document speaks for itself, and that H. D. Smith lacks knowledge or information sufficient to form a belief as to the truth of any statements made in the referenced document.

207. Answering for itself only, H. D. Smith denies the material allegations in Paragraph 207, except it is admitted that the referenced document speaks for itself, and that H. D. Smith lacks knowledge or information sufficient to form a belief as to the truth of any statements made in the referenced document.

208. Answering for itself only, H. D. Smith admits that it has recognized that opioid misuse, abuse, and addiction are a problem, and that it has certain responsibilities with respect to suspicious orders from its customers. H. D. Smith denies any remaining material allegation not expressly admitted.

209. Paragraph 209 is not directed to H. D. Smith and no response from it is required.

210. Paragraph 210 is not directed to H. D. Smith and no response from it is required.

211. Answering for itself only, H. D. Smith denies the material allegations directed at it in Paragraph 211.

2. Prior Regulatory Actions Against Distributor Defendants for Failing to Prevent Diversion

212. Answering for itself only, H. D. Smith denies the allegation that it has “recklessly or negligently allowed diversion.” Further answering, H. D. Smith denies that its conduct “has resulted in numerous civil fines and other penalties.”

a. Cardinal

213. Paragraph 213 is not directed to H. D. Smith and no response from it is required.

214. Paragraph 214 is not directed to H. D. Smith and no response from it is required.

215. Paragraph 215 is not directed to H. D. Smith and no response from it is required.

216. Paragraph 216 is not directed to H. D. Smith and no response from it is required.

217. Paragraph 217 is not directed to H. D. Smith and no response from it is required.

b. McKesson

218. Paragraph 218 is not directed to H. D. Smith and no response from it is required.

219. Paragraph 219 is not directed to H. D. Smith and no response from it is required.

220. Paragraph 220 is not directed to H. D. Smith and no response from it is required.

c. AmerisourceBergen

221. Paragraph 221 is not directed to H. D. Smith and no response from it is required.

222. Paragraph 222 is not directed to H. D. Smith and no response from it is required.

223. Paragraph 223 is not directed to H. D. Smith and no response from it is required.

3. Diversion Manufacturer Defendants Violated Their Duties in Oklahoma

224. With respect to the averments set forth in Paragraph 224, those averments allege conclusions of law to which no response is required. To the extent a response is deemed

necessary, answering for itself only, H. D. Smith denies the material allegations in Paragraph 224.

225. With respect to the averments set forth in Paragraph 225, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering for itself only, H. D. Smith denies the material allegations in Paragraph 225.

226. Answering for itself only, H. D. Smith denies the material allegations directed at it in Paragraph 226.

227. With respect to the averments set forth in Paragraph 227, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering for itself only, H. D. Smith denies the material allegations in Paragraph 227.

228. Paragraph 228 is not directed to H. D. Smith and no response from it is required. To the extent a response is deemed necessary, H. D. Smith lacks knowledge or information sufficient to form a belief about the truth or falsity of the material allegations of Paragraph 228.

229. Paragraph 229 is not directed to H. D. Smith and no response from it is required. To the extent a response is deemed necessary, H. D. Smith lacks knowledge or information sufficient to form a belief about the truth or falsity of the material allegations of Paragraph 229.

4. Despite Prior Regulatory Actions, Distributor Defendants Violated Their Duties in Oklahoma

230. Answering only for itself, H. D. Smith denies the material allegations directed at it in Paragraph 230.

231. Answering only for itself, H. D. Smith denies the material allegations directed at it in Paragraph 231.

232. Answering only for itself, H. D. Smith denies the material allegations directed at it in Paragraph 232.

233. Answering only for itself, H. D. Smith denies the material allegations directed at it in Paragraph 233.

234. Answering only for itself, H. D. Smith denies the material allegations directed at it in Paragraph 234.

235. With respect to the averments set forth in Paragraph 235, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering for itself only, H. D. Smith denies the material allegations directed at it in Paragraph 235.

236. With respect to the averments set forth in Paragraph 236, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering for itself only, H. D. Smith denies the material allegations directed at it in Paragraph 236.

B. Pharmacy Defendants Understood Their Duties and Violated Them Anyway

1. Pharmacy Defendants Understood and Acknowledged Their Duties

237. Paragraph 237 is not directed to H. D. Smith and no response from it is required.

238. Paragraph 238 is not directed to H. D. Smith and no response from it is required.

239. Paragraph 239 is not directed to H. D. Smith and no response from it is required.

240. Paragraph 240 is not directed to H. D. Smith and no response from it is required.

241. Paragraph 241 is not directed to H. D. Smith and no response from it is required.

242. Paragraph 242 is not directed to H. D. Smith and no response from it is required.

243. Paragraph 243 is not directed to H. D. Smith and no response from it is required.

244. Paragraph 244 is not directed to H. D. Smith and no response from it is required.

2. Prior Regulatory Actions Against Pharmacy Defendants for Failing to Prevent Diversion

- 245. Paragraph 245 is not directed to H. D. Smith and no response from it is required.
- 246. Paragraph 246 is not directed to H. D. Smith and no response from it is required.

a. CVS

- 247. Paragraph 247 is not directed to H. D. Smith and no response from it is required.
- 248. Paragraph 248 is not directed to H. D. Smith and no response from it is required.
- 249. Paragraph 249 is not directed to H. D. Smith and no response from it is required.
- 250. Paragraph 250 is not directed to H. D. Smith and no response from it is required.
- 251. Paragraph 251 is not directed to H. D. Smith and no response from it is required.
- 252. Paragraph 252 is not directed to H. D. Smith and no response from it is required.

b. Walgreens

- 253. Paragraph 253 is not directed to H. D. Smith and no response from it is required.
- 254. Paragraph 254 is not directed to H. D. Smith and no response from it is required.
- 255. Paragraph 255 is not directed to H. D. Smith and no response from it is required.

c. Walmart

- 256. Paragraph 256 is not directed to H. D. Smith and no response from it is required.

3. Despite Prior Regulatory Actions, Pharmacy Defendants Continue to Violate Their Duties

- 257. Paragraph 257 is not directed to H. D. Smith and no response from it is required.
- 258. Paragraph 258 is not directed to H. D. Smith and no response from it is required.
- 259. Paragraph 259 is not directed to H. D. Smith and no response from it is required.
- 260. Paragraph 260 is not directed to H. D. Smith and no response from it is required.
- 261. Paragraph 261 is not directed to H. D. Smith and no response from it is required.
- 262. Paragraph 262 is not directed to H. D. Smith and no response from it is required.

VI. DEFENDANTS' MISCONDUCT HAS INJURED AND CONTINUES TO INJURE THE NATION AND ITS CITIZENS

263. Answering for itself only, H. D. Smith denies the material allegations of Paragraph 263 directed at it.

A. Marketing Manufacturer Defendants' Misconduct Has Injured and Continues to Injure the Nation and Its Citizens

264. Paragraph 264 is not directed to H. D. Smith and no response from it is required.

265. Paragraph 265 is not directed to H. D. Smith and no response from it is required.

266. Paragraph 266 is not directed to H. D. Smith and no response from it is required.

267. Paragraph 267 is not directed to H. D. Smith and no response from it is required.

268. Paragraph 268 is not directed to H. D. Smith and no response from it is required.

269. Paragraph 269 is not directed to H. D. Smith and no response from it is required.

270. Paragraph 270 is not directed to H. D. Smith and no response from it is required.

271. Paragraph 271 is not directed to H. D. Smith and no response from it is required.

272. Paragraph 272 is not directed to H. D. Smith and no response from it is required.

273. Paragraph 273 is not directed to H. D. Smith and no response from it is required.

B. Diversion Manufacturer Defendants' and Distributor Defendants' Misconduct Has Injured and Continues to Injure the Nation and Its Citizens

274. With respect to the averments set forth in Paragraph 274, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, and answering for itself only, H. D. Smith denies any allegation, implication, or inference that it violated any duties under Federal or Oklahoma law or that any act or omission by it caused or contributed to any of the Nation's damages.

275. With respect to the averments set forth in Paragraph 275, those averments allege conclusions of law to which no response is required. To the extent a response is deemed

necessary, and answering for itself only, H. D Smith admits the allegation that injuries such as “addiction, overdoses, and death” can arise from diversion, but it denies any allegation, inference, or implication that it has engaged in any acts or omissions that have caused the Nation to incur any damages for which it is liable.

276. With respect to the averments set forth in Paragraph 276, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, and answering for itself only, H. D. Smith denies any allegation, inference, or implication that it has engaged in any acts or omissions that have contributed to the Nation’s opioid epidemic or any of the Nation’s damages.

277. With respect to the averments set forth in Paragraph 277, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, and answering for itself only, H. D. Smith denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation’s damages.

278. Answering for itself only, H. D. Smith admits the allegation that it was “aware of widespread prescription opioid abuse in and around the Nation,” but denies the allegation that it “persisted in a pattern of distributing commonly-abused and diverted opioids in places—and in such quantities, and with such frequency—that [it] knew or should have known these opioids were not being prescribed and consumed for legitimate medical purposes.” Further answering, H. D. Smith denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation’s damages.

279. Answering for itself only, H. D. Smith denies the material allegations directed at it in Paragraph 279. Further answering, H. D. Smith states that it adhered to effective controls to

guard against diversion, therefore, it denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation's damages.

280. With respect to the averments set forth in Paragraph 280, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, and answering for itself only, H. D. Smith denies the material allegations directed at it in Paragraph 280.

281. With respect to the averments set forth in Paragraph 281, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, and answering for itself only, H. D. Smith denies the material allegations directed at it in Paragraph 281.

282. Answering for itself only, H. D. Smith denies that it engaged in the activities alleged in Paragraph 282. Further answering, H. D. Smith lacks knowledge or information sufficient to form a belief about the truth or falsity of the remaining allegations in Paragraph 282 and denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation's damages.

283. With respect to the averments set forth in Paragraph 283, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, and answering for itself only, H. D. Smith denies any allegation, inference, or implication that it has engaged in any acts or omissions that would make it "reasonably foreseeable to [it] that the Nation would be forced to bear substantial expenses as a result of [its] acts." Further answering, H. D. Smith denies that the kinds of damages for alleged "substantial expenses" the Nation has alleged in Paragraph 283 are recoverable in this action.

284. With respect to the averments set forth in Paragraph 284, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, and answering for itself only, H. D. Smith denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation's damages.

C. Pharmacy Defendants' Misconduct Has Injured and Continues to Injure the Nation and Its Citizens

285. Paragraph 285 is not directed to H. D. Smith and no response from it is required.

286. Paragraph 286 is not directed to H. D. Smith and no response from it is required.

287. Paragraph 287 is not directed to H. D. Smith and no response from it is required.

288. Paragraph 288 is not directed to H. D. Smith and no response from it is required.

289. Paragraph 289 is not directed to H. D. Smith and no response from it is required.

290. Paragraph 290 is not directed to H. D. Smith and no response from it is required.

291. Paragraph 291 is not directed to H. D. Smith and no response from it is required.

292. Paragraph 292 is not directed to H. D. Smith and no response from it is required.

293. Paragraph 293 is not directed to H. D. Smith and no response from it is required.

D. Defendants' Misconduct Has Damaged the Nation and Its Citizens

294. With respect to the averments set forth in Paragraph 294, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, H. D. Smith denies any allegation, implication, or inference that any act or omission by it was or is a direct and proximate cause of the damages set forth in Paragraph 294. H. D. Smith is without knowledge to as to the truth or falsity of the remaining material allegations in Paragraph 294.

VII. FACTS PERTAINING TO CLAIMS UNDER RICO

295. Answering for itself only, H. D. Smith denies that it engaged in the activities alleged in Paragraph 295.

A. The Opioid Marketing Enterprise

1. The Common Purpose and Scheme of the Opioid Marketing Enterprise

296. Paragraph 296 is not directed to H. D. Smith and no response from it is required.

297. Paragraph 297 is not directed to H. D. Smith and no response from it is required.

298. Paragraph 298 is not directed to H. D. Smith and no response from it is required.

299. Paragraph 299 is not directed to H. D. Smith and no response from it is required.

300. Paragraph 300 is not directed to H. D. Smith and no response from it is required.

301. Paragraph 301 is not directed to H. D. Smith and no response from it is required.

302. Paragraph 302 is not directed to H. D. Smith and no response from it is required.

303. Paragraph 303 is not directed to H. D. Smith and no response from it is required.

2. The Conduct of the Opioid Marketing Enterprise

304. Paragraph 304 is not directed to H. D. Smith and no response from it is required.

305. Paragraph 305 is not directed to H. D. Smith and no response from it is required.

306. Paragraph 306 is not directed to H. D. Smith and no response from it is required.

307. Paragraph 307 is not directed to H. D. Smith and no response from it is required.

308. Paragraph 308 is not directed to H. D. Smith and no response from it is required.

309. Paragraph 309 is not directed to H. D. Smith and no response from it is required.

310. Paragraph 310 is not directed to H. D. Smith and no response from it is required.

311. Paragraph 311 is not directed to H. D. Smith and no response from it is required.

312. Paragraph 312 is not directed to H. D. Smith and no response from it is required.

- 313. Paragraph 313 is not directed to H. D. Smith and no response from it is required.
- 314. Paragraph 314 is not directed to H. D. Smith and no response from it is required.
- 315. Paragraph 315 is not directed to H. D. Smith and no response from it is required.
- 316. Paragraph 316 is not directed to H. D. Smith and no response from it is required.
- 317. Paragraph 317 is not directed to H. D. Smith and no response from it is required.
- 318. Paragraph 318 is not directed to H. D. Smith and no response from it is required.

3. The Pattern of Racketeering Activity

- 319. Paragraph 319 is not directed to H. D. Smith and no response from it is required.
- 320. Paragraph 320 is not directed to H. D. Smith and no response from it is required.
- 321. Paragraph 321 is not directed to H. D. Smith and no response from it is required.
- 322. Paragraph 322 is not directed to H. D. Smith and no response from it is required.
- 323. Paragraph 323 is not directed to H. D. Smith and no response from it is required.
- 324. Paragraph 324 is not directed to H. D. Smith and no response from it is required.
- 325. Paragraph 325 is not directed to H. D. Smith and no response from it is required.
- 326. Paragraph 326 is not directed to H. D. Smith and no response from it is required.
- 327. Paragraph 327 is not directed to H. D. Smith and no response from it is required.
- 328. Paragraph 328 is not directed to H. D. Smith and no response from it is required.

B. The Opioid Supply Chain Enterprise

1. The Common Purpose and Scheme of the Opioid Supply Chain Enterprise

- 329. With respect to the averments set forth in Paragraph 329, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies that it engaged in the activities alleged in

Paragraph 329. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 329.

330. Answering only for itself, H. D. Smith denies the material allegations of Paragraph 330, except it is admitted that the referenced document is a writing that speaks for itself. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 329.

331. With respect to the averments set forth in Paragraph 331, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 331 direct against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 331.

332. With respect to the averments set forth in Paragraph 332, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 332 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 332.

2. The Conduct of the Opioid Supply Chain Enterprise

333. With respect to the averments set forth in Paragraph 333, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 333 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 333.

334. With respect to the averments set forth in Paragraph 334 and its subparts, those averments allege conclusions of law to which no response is required. To the extent a response

is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 334 and its subparts directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 334 and its subparts.

335. With respect to the averments set forth in Paragraph 335, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 335 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 335.

336. With respect to the averments set forth in Paragraph 336, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 336 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 336.

3. The Pattern of Racketeering Activity

337. With respect to the averments set forth in Paragraph 337, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 337 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 337.

338. With respect to the averments set forth in Paragraph 338, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 338 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 338.

339. With respect to the averments set forth in Paragraph 339, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 339 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 339.

340. With respect to the averments set forth in Paragraph 340 and its subparts, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 340 and its subparts directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 340 and its subparts.

341. With respect to the averments set forth in Paragraph 341, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 341 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 341.

342. With respect to the averments set forth in Paragraph 342, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 342 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 342.

343. With respect to the averments set forth in Paragraph 343, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in

Paragraph 343 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 343.

344. With respect to the averments set forth in Paragraph 344, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 344 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 344.

345. With respect to the averments set forth in Paragraph 345, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 345 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 345.

346. With respect to the averments set forth in Paragraph 346, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 346 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 346.

347. With respect to the averments set forth in Paragraph 347, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 347 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 347.

348. With respect to the averments set forth in Paragraph 348, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 348 and specifically denies that it was subject to any enforcement actions or fined. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 348.

349. With respect to the averments set forth in Paragraph 349, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 349 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 349.

C. Effects of the Opioid Marketing Enterprise and the Opioid Supply Chain Enterprise

350. With respect to the averments set forth in Paragraph 350, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 350 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 350.

351. With respect to the averments set forth in Paragraph 351, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 351 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 351.

352. With respect to the averments set forth in Paragraph 352, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 352 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 352.

CLAIMS FOR RELIEF

COUNT I

VIOLATION OF RICO, 18 U.S.C. § 1961, et seq.
OPIOID MARKETING ENTERPRISE
(Against the Marketing Manufacturer Defendants)

- 353. Paragraph 353 is not directed to H. D. Smith and no response from it is required.
- 354. Paragraph 354 is not directed to H. D. Smith and no response from it is required.
- 355. Paragraph 355 is not directed to H. D. Smith and no response from it is required.
- 356. Paragraph 356 is not directed to H. D. Smith and no response from it is required.
- 357. Paragraph 357 is not directed to H. D. Smith and no response from it is required.
- 358. Paragraph 358 is not directed to H. D. Smith and no response from it is required.
- 359. Paragraph 359 is not directed to H. D. Smith and no response from it is required.
- 360. Paragraph 360 is not directed to H. D. Smith and no response from it is required.
- 361. Paragraph 361 is not directed to H. D. Smith and no response from it is required.
- 362. Paragraph 362 is not directed to H. D. Smith and no response from it is required.
- 363. Paragraph 363 is not directed to H. D. Smith and no response from it is required.
- 364. Paragraph 364 is not directed to H. D. Smith and no response from it is required.
- 365. Paragraph 365 is not directed to H. D. Smith and no response from it is required.
- 366. Paragraph 366 is not directed to H. D. Smith and no response from it is required.
- 367. Paragraph 367 is not directed to H. D. Smith and no response from it is required.

368. Paragraph 368 is not directed to H. D. Smith and no response from it is required.
369. Paragraph 369 is not directed to H. D. Smith and no response from it is required.
370. Paragraph 370 is not directed to H. D. Smith and no response from it is required.
371. Paragraph 371 is not directed to H. D. Smith and no response from it is required.
372. Paragraph 372 is not directed to H. D. Smith and no response from it is required.
373. Paragraph 373 is not directed to H. D. Smith and no response from it is required.
374. Paragraph 374 is not directed to H. D. Smith and no response from it is required.
375. Paragraph 375 is not directed to H. D. Smith and no response from it is required.
376. Paragraph 376 is not directed to H. D. Smith and no response from it is required.
377. Paragraph 377 is not directed to H. D. Smith and no response from it is required.
378. Paragraph 378 is not directed to H. D. Smith and no response from it is required.
379. Paragraph 379 is not directed to H. D. Smith and no response from it is required.

COUNT II

**VIOLATION OF RICO, 18 U.S.C. § 1961, *et seq.*
OPIOID SUPPLY CHAIN ENTERPRISE
(Against All Defendants)**

380. H. D. Smith incorporates by reference all other responses of its Answer as if fully set forth herein.

381. With respect to the averments set forth in Paragraph 381, those averments allege conclusions of law to which no response is required.

382. With respect to the averments set forth in Paragraph 382, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 382 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 382.

383. With respect to the averments set forth in Paragraph 383, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 383 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 383.

384. With respect to the averments set forth in Paragraph 384, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 384 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 384.

385. With respect to the averments set forth in Paragraph 385, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 385 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 385.

386. With respect to the averments set forth in Paragraph 386, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 386 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 386.

387. With respect to the averments set forth in Paragraph 387, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in

Paragraph 387 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 387.

388. With respect to the averments set forth in Paragraph 388, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 388 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 388.

389. With respect to the averments set forth in Paragraph 389, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 389 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 389.

390. With respect to the averments set forth in Paragraph 390, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 390 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 390.

391. With respect to the averments set forth in Paragraph 391, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 391 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 391.

392. With respect to the averments set forth in Paragraph 392 and its subparts, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 392 and its subparts directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 392 and its subparts.

393. With respect to the averments set forth in Paragraph 393, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 393 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 393.

394. With respect to the averments set forth in Paragraph 394, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 394 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 394.

395. With respect to the averments set forth in Paragraph 395, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 395 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 395.

396. With respect to the averments set forth in Paragraph 396, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in

Paragraph 396 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 396.

397. With respect to the averments set forth in Paragraph 397, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 397 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 397.

398. With respect to the averments set forth in Paragraph 398, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 398 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 398.

399. With respect to the averments set forth in Paragraph 399, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 399 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 399.

400. With respect to the averments set forth in Paragraph 400, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 400 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 400.

401. With respect to the averments set forth in Paragraph 401, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 401 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 401.

402. With respect to the averments set forth in Paragraph 402, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 402 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 402.

403. With respect to the averments set forth in Paragraph 403, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 403 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 403.

404. With respect to the averments set forth in Paragraph 404, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 404 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 404.

405. With respect to the averments set forth in Paragraph 405, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in

Paragraph 405 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 405.

406. With respect to the averments set forth in Paragraph 406, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 406 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 406.

407. With respect to the averments set forth in Paragraph 407, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 407 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 407.

408. With respect to the averments set forth in Paragraph 408, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 408 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 408.

COUNT III

LANHAM ACT (Against All Defendants)

409. H. D. Smith incorporates by reference all other responses of this Answer as if fully set forth herein.

410. The Court adopted the Report and Recommendation dismissing Plaintiff's claim under the Lanham Act [Docs. 1499, 1680], therefore no response is required. To the extent an

answer is required and with respect to the averments set forth in Paragraph 410, those averments allege conclusions of law to which no response is required.

411. The Court adopted the Report and Recommendation dismissing Plaintiff's claim under the Lanham Act [Docs. 1499, 1680], therefore no response is required. To the extent an answer is required and with respect to the averments set forth in Paragraph 411, those averments allege conclusions of law. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 411 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 411.

412. The Court adopted the Report and Recommendation dismissing Plaintiff's claim under the Lanham Act [Docs. 1499, 1680], therefore no response is required. To the extent an answer is required and with respect to the averments set forth in Paragraph 412, those averments allege conclusions of law. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 412 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 412.

413. The Court adopted the Report and Recommendation dismissing Plaintiff's claim under the Lanham Act [Docs. 1499, 1680], therefore no response is required. To the extent an answer is required and with respect to the averments set forth in Paragraph 413, those averments allege conclusions of law. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 413 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 413.

414. The Court adopted the Report and Recommendation dismissing Plaintiff's claim under the Lanham Act [Docs. 1499, 1680], therefore no response is required. To the extent an answer is required and with respect to the averments set forth in Paragraph 414, those averments allege conclusions of law. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 414 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 414.

415. The Court adopted the Report and Recommendation dismissing Plaintiff's claim under the Lanham Act [Docs. 1499, 1680], therefore no response is required. To the extent an answer is required and with respect to the averments set forth in Paragraph 415, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 415 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 415.

416. The Court adopted the Report and Recommendation dismissing Plaintiff's claim under the Lanham Act [Docs. 1499, 1680], therefore no response is required. To the extent an answer is required and with respect to the averments set forth in Paragraph 416, those averments allege conclusions of law. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 416 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 416.

417. The Court adopted the Report and Recommendation dismissing Plaintiff's claim under the Lanham Act [Docs. 1499, 1680], therefore no response is required. To the extent an

answer is required and with respect to the averments set forth in Paragraph 417, those averments allege conclusions of law. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 417 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 417.

418. The Court adopted the Report and Recommendation dismissing Plaintiff's claim under the Lanham Act [Docs. 1499, 1680], therefore no response is required. To the extent an answer is required and with respect to the averments set forth in Paragraph 418, those averments allege conclusions of law. To the extent a response is deemed necessary, answering only for itself, H. D. Smith denies the material allegations set forth in Paragraph 418 directed against it. H. D. Smith is without knowledge as to the truth or falsity of the remaining allegations in Paragraph 418.

COUNT IV

NUISANCE (Against Marketing Manufacturer Defendants)

419. H. D. Smith incorporates by reference all other responses of this Answer as if fully set forth herein.

420. Paragraph 420 is not directed to H. D. Smith and no response from it is required.
421. Paragraph 421 is not directed to H. D. Smith and no response from it is required.
422. Paragraph 422 is not directed to H. D. Smith and no response from it is required.
423. Paragraph 423 is not directed to H. D. Smith and no response from it is required.
424. Paragraph 424 is not directed to H. D. Smith and no response from it is required.
425. Paragraph 425 is not directed to H. D. Smith and no response from it is required.
426. Paragraph 426 is not directed to H. D. Smith and no response from it is required.

- 427. Paragraph 427 is not directed to H. D. Smith and no response from it is required.
- 428. Paragraph 428 is not directed to H. D. Smith and no response from it is required.
- 429. Paragraph 429 is not directed to H. D. Smith and no response from it is required.
- 430. Paragraph 430 is not directed to H. D. Smith and no response from it is required.
- 431. Paragraph 431 is not directed to H. D. Smith and no response from it is required.
- 432. Paragraph 432 is not directed to H. D. Smith and no response from it is required.

COUNT V

**NEGLIGENCE AND NEGLIGENCE PER SE
(Against Marketing Manufacturer Defendants)**

- 433. H. D. Smith incorporates by reference all other responses of this Answer as if fully set forth herein.
- 434. Paragraph 434 is not directed to H. D. Smith and no response from it is required.
- 435. Paragraph 435 is not directed to H. D. Smith and no response from it is required.
- 436. Paragraph 436 is not directed to H. D. Smith and no response from it is required.
- 437. Paragraph 437 is not directed to H. D. Smith and no response from it is required.
- 438. Paragraph 438 is not directed to H. D. Smith and no response from it is required.
- 439. Paragraph 439 is not directed to H. D. Smith and no response from it is required.
- 440. Paragraph 440 is not directed to H. D. Smith and no response from it is required.
- 441. Paragraph 441 is not directed to H. D. Smith and no response from it is required.
- 442. Paragraph 442 is not directed to H. D. Smith and no response from it is required.
- 443. Paragraph 443 is not directed to H. D. Smith and no response from it is required.
- 444. Paragraph 444 is not directed to H. D. Smith and no response from it is required.
- 445. Paragraph 445 is not directed to H. D. Smith and no response from it is required.

COUNT VI

UNJUST ENRICHMENT
(Against Marketing Manufacturer Defendants)

446. H. D. Smith incorporates by reference all other responses of this Answer as if fully set forth herein.

447. Paragraph 447 is not directed to H. D. Smith and no response from it is required.

448. Paragraph 448 is not directed to H. D. Smith and no response from it is required.

449. Paragraph 449 is not directed to H. D. Smith and no response from it is required.

450. Paragraph 450 is not directed to H. D. Smith and no response from it is required.

COUNT VII

NUISANCE
(Against Diversion Defendants)

451. H. D. Smith incorporates by reference all other responses of this Answer as if fully set forth herein.

452. Answering only for itself, H. D. Smith denies the material allegations of Paragraph 452 and its subparts.

453. Answering only for itself, H. D. Smith denies the material allegations of Paragraph 453 and its subparts.

454. Answering only for itself, H. D. Smith denies the material allegations of Paragraph 454 and its subparts.

455. Answering only for itself, H. D. Smith denies the material allegations of Paragraph 455.

456. Answering only for itself, H. D. Smith denies the material allegations of Paragraph 456.

457. Answering for itself only, H. D. Smith lacks knowledge or information sufficient to for a belief about the truth or falsity of the material allegations in Paragraph 457 that “[t]he nuisance has undermined, is undermining, and will continue to undermine the Nation citizens’ public health, quality of life, and safety. It has resulted in increased crime and property damage within the Nation. It has resulted in high rates of addiction, overdoses, and dysfunction within Delaware families and entire communities.” Further answering, H. D. Smith denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation’s damages.

458. Answering for itself only, H. D. Smith lacks knowledge or information sufficient to for a belief about the truth or falsity of the material allegations in Paragraph 458. Further answering, H. D. Smith denies any allegation, inference, or implication that it has engaged in any acts or omissions that have contributed to the “opioid epidemic.” Further answering, H. D. Smith denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation’s damages.

459. Answering for itself only, H. D. Smith admits that it is registered as a wholesale drug distributor in the chain of distribution of Schedule II controlled substances in Oklahoma, but denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation’s damages.

460. Answering for itself only, H. D. Smith lacks knowledge or information sufficient to for a belief about the truth or falsity of the material allegations in Paragraph 460. Further answering, H. D. Smith denies any allegation, inference, or implication that it has engaged in any acts or omissions that have contributed to any acts or omissions that “annoy, injure, and endanger the comfort, repose, health and safety of the Nation, offend decency, and render the

citizens of the Nation insecure in their lives and the use of property.” Further answering, H. D. Smith denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation’s damages.

461. Answering for itself only, H. D. Smith denies the material allegations of Paragraph 461. Further answering, H. D. Smith denies any allegation, implication, or inference that any act or omission by it constituted a “nuisance-causing” activity. Further answering, H. D. Smith denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation’s damages.

462. Answering for itself only, H. D. Smith admits that it is registered as a wholesale drug distributor in the chain of distribution of Schedule II controlled substances in Oklahoma, but denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation’s damages.

463. Answering only for itself, H. D. Smith denies the material allegations in Paragraph 463.

464. Answering only for itself, H. D. Smith denies the material allegations in Paragraph 464.

COUNT VIII

NEGLIGENCE AND NEGLIGENCE PER SE (Against Diversion Defendants)

465. H. D. Smith incorporates by reference all other responses of this Answer as if fully set forth herein.

466. With respect to the material allegations in Paragraph 466, those allegations contain conclusions law to which no response is required. To the extent a response is deemed necessary, and answering for itself only, H. D. Smith denies any allegation, implication, or

inference that it failed to act reasonably or that any act or omission by it caused or contributed to any of the Nation's damages.

467. With respect to the material allegations in Paragraph 467, those allegations contain conclusions law to which no response is required. To the extent a response is deemed necessary, and answering for itself only, H. D. Smith denies any allegation, implication, or inference that it failed to act reasonably or that any act or omission by it caused or contributed to any of the Nation's damages.

468. With respect to the averments set forth in Paragraph 468 and its subparts, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, and answering for itself only, H. D. Smith denies the allegations directed against it at Paragraph 468 and its subparts.

469. Answering for itself only with respect to Paragraph 469, H. D. Smith admits that as a registered wholesale distributor in the chain of distribution of Schedule II controlled substances, it assumed statutory and regulatory duties with respect to controlling the sale and distribution of prescription opioids, but denies any allegation, implication, or inference that it violated any such duty. Further answering, H. D. Smith denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation's damages.

470. Answering for itself only, H. D. Smith admits that it sold prescription opioids in the supply chain, but denies the material allegations in Paragraph 470 that "it knew or should have known that (a) there was a substantial likelihood that many of the sales were for non-medical purposes." With respect to the allegation H. D. Smith knew or should have known that "(b) opioids are an inherently dangerous product when used for non-medical purposes," H. D. Smith states that this averment alleges a conclusion of law to which no response is required. To

the extent a response is deemed necessary, H. D. Smith denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation's damages.

471. Answering for itself only, H. D. Smith denies the material allegations of Paragraph 471.

472. Answering for itself only, H. D. Smith denies the material allegations of Paragraph 472.

473. Answering for itself only, H. D. Smith denies the material allegations of Paragraph 473.

474. With respect to the averments set forth in Paragraph 474, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering for itself only, H. D. Smith denies the allegations directed at it in Paragraph 474. Further answering, H. D. Smith denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation's damages.

475. Pursuant to the Court's June 13, 2019 Opinion and Order [Doc. 1680], the Nation's claim for negligence per se has been dismissed. Accordingly, no response is needed to this allegation.

476. With respect to the averments set forth in Paragraph 476, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering for itself only, H. D. Smith denies the allegations directed at it in Paragraph 476. Further answering, H. D. Smith denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation's damages.

477. H. D. Smith lacks knowledge or information sufficient to form a belief as to the truth of the material allegations of Paragraph 477. Further answering, H. D. Smith denies any

allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation's damages.

478. Answering for itself only, H. D. Smith denies the material allegations of paragraph 478. Further answering, H. D. Smith denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation's damages.

COUNT IX

UNJUST ENRICHMENT (Against Diversion Defendants)

479. H. D. Smith incorporates by reference all other responses of this Answer as if fully set forth herein.

480. With respect to the material allegations of Paragraph 480, H. D. Smith lacks knowledge or information sufficient to form a belief as to the truth or falsity of Plaintiff's allegation that “[t]he Nation has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Diversion Defendants' conduct.” With respect to the remaining allegations directed at H. D. Smith, and answering for itself only, H. D. Smith denies the material allegations of Paragraph 480.

481. With respect to the material allegations of Paragraph 481, H. D. Smith lacks knowledge or information sufficient to form a belief as to the truth or falsity of Plaintiff's allegation regarding “[t]he Nation's expenditures in providing healthcare services to people who use opioids.” With respect to the allegations directed at H. D. Smith, and answering for itself only, H. D. Smith denies the remaining material allegations of Paragraph 481. Further answering, H. D. Smith denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation's damages.

482. Answering for itself only, H. D. Smith denies the material allegations of Paragraph 482. Further answering, H. D. Smith denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation's damages.

483. Answering for itself only, H. D. Smith denies the material allegations directed at it in Paragraph 483.

484. Answering for itself only, H. D. Smith denies the material allegations directed at it in Paragraph 484. Further answering, H. D. Smith denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation's damages.

COUNT X

**CIVIL CONSPIRACY
(Against All Defendants)**

485. H. D. Smith incorporates by reference all other responses of this Answer as if fully set forth herein.

486. Paragraph 486 is not directed to H. D. Smith and no response from it is required.

487. With respect to the averments set forth in Paragraph 487 of the Complaint, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering for itself only, H. D. Smith denies the material allegations directed at it in Paragraph 487. Further answering, H. D. Smith denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation's damages.

488. Answering for itself only, H. D. Smith denies the material allegations directed at it in Paragraph 488.

489. Answering for itself only, H. D. Smith denies the material allegations directed at it in Paragraph 489.

490. With respect to the averments set forth in Paragraph 490 of the Complaint, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering for itself only, H. D. Smith denies the material allegations of Paragraph 490. Further answering, H. D. Smith denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation's damages.

491. With respect to the averments set forth in Paragraph 491 of the Complaint, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering for itself only, H. D. Smith denies the material allegations of Paragraph 491. Further answering, H. D. Smith denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation's damages.

492. With respect to the averments set forth in Paragraph 492 of the Complaint, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering for itself only, H. D. Smith denies the material allegations of Paragraph 492. Further answering, H. D. Smith denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation's damages.

493. With respect to the averments set forth in Paragraph 493 of the Complaint, those averments allege conclusions of law to which no response is required. To the extent a response is deemed necessary, answering for itself only, H. D. Smith denies the material allegations of Paragraph 493.

PRAYER FOR RELIEF

To the extent a response to the Prayer for Relief is required, H. D. Smith denies any allegation, implication, or inference that any act or omission by it caused or contributed to any of the Nation's damages and requests judgment in its favor and such other relief as the Court deems equitable and just.

ADDITIONAL AND/OR AFFIRMATIVE DEFENSES

H. D. Smith asserts the following additional and/or affirmative defenses in response to the allegations in the FAC. In asserting these affirmative defenses, H. D. Smith does not assume the burden to establish any fact or proposition where that burden is properly imposed on Plaintiff.

1. The FAC fails to state a claim upon which relief can be granted.
2. The Court lacks subject matter jurisdiction based on the failure to exhaust administrative or tribal remedies.
3. Plaintiff's claims are barred, in whole or in part, by the political question and separation of powers doctrines.
4. The Plaintiff lacks standing to assert all or some of its claims in this lawsuit.
5. Plaintiff's claims are barred, in whole or in part, because the harm alleged was proximately caused by the negligence, gross negligence, or intentional and malicious acts of intervening third parties not under the control of H. D. Smith.
6. Plaintiff's claims are barred, in whole or in part, by contributory or comparative negligence and contributory or comparative fault.
7. Plaintiff's claims are barred because Plaintiff failed to join one or more indispensable parties.
8. Plaintiff's claims against H. D. Smith are barred because H. D. Smith has complied with all applicable laws or regulations of the federal government and the State of Oklahoma.
9. Plaintiff's claims against H. D. Smith are barred, in whole or in part, by the applicable statutes of limitations and repose.

10. Plaintiff's claims against H. D. Smith are barred, in whole or in part, by the doctrines of laches, estoppel, waiver, release, unclean hands, accord and satisfaction, consent, agreement, ratification, contributory negligence, illegality, and any other matter constituting an avoidance or affirmative defense.

11. Plaintiff's claims against H. D. Smith fail under the bulk supplier doctrine, sophisticated user defense, and the learned intermediary doctrine.

12. Plaintiff's negligence and nuisance claims are barred by the economic-loss doctrine.

13. H. D. Smith relies upon the doctrine of abnormal use, misuse, and unintended use that was inconsistent with the product-use instructions included with the relevant products distributed by H. D. Smith or with other known safety practices.

14. H. D. Smith asserts the defense of absence of wanton, willful, or malicious conduct.

15. H. D. Smith at all times complied with all applicable governmental and industry rules, regulations, and standards when it distributed any relevant product into Oklahoma and/or the Nation.

16. H. D. Smith asserts that any loss or damage alleged by Plaintiff was proximately caused or contributed to by a superseding or intervening cause or causes other than an act or omission on the part of H. D. Smith, including intentional criminal acts of third persons, and, accordingly, Plaintiff is barred from any recovery herein. In the alternative, the damages must be apportioned such that H. D. Smith is only held responsible for those damages for which it is found responsible under Oklahoma law, if any.

17. H. D. Smith denies all types of causation, including cause in fact, proximate cause, and producing cause, with respect to the claims asserted against H. D. Smith.

18. Plaintiff's claims are barred in whole or in part because no statement or conduct of H. D. Smith was misleading, unfair, or deceptive.

19. H. D. Smith is not liable for any injury allegedly caused to Plaintiff by the products in question because all formulations, labeling, and design of the products complied with mandatory safety standards or regulations adopted and promulgated by the federal government, or an agency of the federal government, applicable to the products at the time of manufacture and that governed the product risk that allegedly caused the purported harm.

20. H. D. Smith adopts and asserts the defense of comparative assumption of risk and/or comparative fault.

21. Plaintiff's claims are barred, in whole or in part, because they violate the *Ex Post Facto* clauses of Article I of the United States Constitution, insofar as Plaintiff seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

22. H. D. Smith is entitled to an offset, should any damages be awarded against it, in the amount of damages or settlement recovered by Plaintiff with respect to the same alleged injuries.

23. The attorney fees, cost, and expenses sought to be recovered by Plaintiff in the FAC are neither reasonable nor necessary, and Plaintiff is not entitled to any attorneys' fees, costs, pre-judgment interest, or post-judgment interest.

24. Plaintiff's claims for (i) statutory public nuisance, (ii) common law public nuisance, and (iii) negligence are abrogated by the Oklahoma Product Liability Act.

25. To the extent Plaintiff asserts a statutory public nuisance claim, it fails because H. D. Smith's conduct complied with Oklahoma controlled-substance regulations, and, thus, H. D. Smith cannot be liable under 50 Okla. Stat. § 504.

26. Plaintiff's claims against H. D. Smith are misjoined with Plaintiff's claims against other defendants and must be severed.

27. Plaintiff's claims are barred, in whole or in part, by Plaintiff's failure to mitigate damages.

28. Plaintiff's claims are barred, in whole or in part, because the claims are speculative, remote, and because it is impossible to ascertain and allocate the alleged damages.

29. To the extent that Plaintiff seeks equitable relief against H. D. Smith, Plaintiff is not entitled to such relief because Plaintiff has an adequate remedy at law.

30. Plaintiff's claims for unjust enrichment are barred because H. D. Smith has not accepted or retained any benefits under circumstances where it would be inequitable for H. D. Smith to do so.

31. Plaintiff's claims for unjust enrichment are barred because Plaintiff has no authority to bring such claims on behalf of itself or the citizens of the Nation.

32. Plaintiff's claims for unjust enrichment are barred because Plaintiff did not pay H. D. Smith any of the amounts sought.

33. Plaintiff lacks authority to assert the putative *parens patriae* claims on behalf of the citizens of the Nation.

34. Plaintiff's claims are barred, in whole or in part, by the Due Process Clause of the Fifth and Fourteenth Amendments to the United States Constitution and Article II, Sections 7 of

the Oklahoma Constitution because substantive due process forbids the retroactive imposition of changing and unclear legal interpretations of the Oklahoma Uniform Controlled Substances Act.

35. Plaintiff's commencement and prosecution of this action is arbitrary and capricious, and its claims are contrary to the Oklahoma Uniform Controlled Substances Act, and rules and regulations promulgated pursuant to that Act.

36. Plaintiff lacks authority to bring its claims under the Oklahoma Uniform Controlled Substances Act.

37. The FAC fails to state a claim against H. D. Smith because Plaintiff cannot establish a right common to the general public with which H. D. Smith unreasonably interfered.

38. The FAC fails to state a claim upon which relief can be granted for a common-law public nuisance claim because the sale of highly regulated legal products cannot constitute a public nuisance.

39. H. D. Smith asserts its right to litigate punitive damages and offer proof in a separate trial than that which determines liability and compensatory damages.

40. Plaintiff's claims are barred by the statewide-concern doctrine.

41. To the extent Plaintiff asserts a claim for punitive damages against H. D. Smith by virtue of the matters set forth in the FAC, the Plaintiff is not entitled to any punitive damages because it cannot be proved by clear and convincing evidence that the alleged conduct of H. D. Smith was willful, wanton or reckless disregard of the rights of Plaintiff and cannot be assessed to H. D. Smith on the basis of the conduct of another Defendant.

42. Plaintiff's claims for exemplary or punitive damages violate H. D. Smith's rights under the Due Process and Excessive Fines clauses of the Fifth, Sixth, Eighth, and Fourteenth Amendments of the United States Constitution and the analogous provisions of the Oklahoma

State Constitution and under the First Amendment of the United States Constitution and the analogous provisions of the Oklahoma State Constitution.

43. The Plaintiff's claim for punitive damages violates, and is therefore barred by, the provisions of the Constitution of the State of Oklahoma upon the following grounds:

a. It is a violation of the due process and equal protection clauses to impose punitive damages against a civil defendant upon the Plaintiff's satisfaction of a burden of proof less than the burden of proof that is required in criminal cases.

b. The procedures under which punitive damages may be awarded fail to provide a reasonable or substantive limit on the amount of the award which may be levied against this Defendant.

c. The procedures under which punitive damages may be awarded fail to provide specific standards for the amount of the award against this Defendant.

d. The procedures under which punitive damages may be awarded result in the imposition of differing penalties for the same or similar acts.

e. The procedures under which punitive damages may be awarded permit the imposition of such damages in excess of the maximum possible criminal fines for the same or similar acts.

44. H. D. Smith's liability, if any, will not result from its own negligence, intentional acts, or other acts or omissions, and thus H. D. Smith is entitled to indemnity under 12 Okla. Stat. § 12-832.1.

45. Plaintiff's claims are barred because Plaintiff is not the real party in interest.

46. Plaintiff's claims and damages are barred or limited, in whole or in part, by common-law, statutory, and state constitutional constraints on the exercise of police powers by a state, municipality or domestic dependent nation.

47. Plaintiff may be barred by the doctrines of *res judicata* and collateral estoppel from all forms of relief sought in the FAC.

48. Plaintiff's claims are barred or limited by the terms and effect of any applicable Consent Judgment, including by operation of the doctrines of *res judicata* and collateral estoppel, failure to fulfill conditions precedent, failure to provide requisite notice, payment, accord and satisfaction, and compromise and settlement.

49. The FAC, and each alleged claim contained therein, is barred, in whole or in part, because the derivative-injury rule and the remoteness doctrine bar Plaintiff from recovering payments that it allegedly made on behalf of its residents to reimburse any expenses for health care, pharmaceutical care, and other public services.

50. Plaintiff fails to plead that it reimbursed any prescriptions for any opioid distributed by H. D. Smith that harmed patients and should not have been written, or that H. D. Smith's allegedly improper conduct caused any health care provider to write any ineffective or harmful opioid prescriptions.

51. Any verdict or judgment that might be recovered by Plaintiff must be reduced by those amounts that have already indemnified or with reasonable certainty will indemnify Plaintiff in whole or in part for any past or future claimed economic loss from any collateral source or any other applicable law.

52. If H. D. Smith is found liable for Plaintiff's alleged injuries and losses (which liability is specifically denied), the facts will show that Plaintiff's negligence, or the negligence

of any person on whose behalf Plaintiff is asserting claims, is of a greater degree than the combined negligence of any persons, firms or corporation causing its damages and thus its negligence claims are barred. 23 Okla. Stat. § 23-13.

53. If H. D. Smith is found liable for Plaintiff's alleged injuries and losses (which liability is specifically denied), H. D. Smith is entitled to a reduction of damages based on Plaintiff's own negligence or the negligence of any person on whose behalf Plaintiff is asserting claims. 23 Okla. Stat. § 23-14.

54. If H. D. Smith is found liable for Plaintiff's alleged injuries and losses (which liability is specifically denied), H. D. Smith would be liable only for its proportionate share of the damages that represent economic loss proximately caused by H. D. Smith. 23 Okla. Stat. § 23-15.

55. A percentage of Plaintiff's alleged injury or loss, if proven, is attributable to (i) Plaintiff, (ii) other parties from whom Plaintiff seeks recovery, and (iii) persons from whom Plaintiff does not seek recovery in this action, including, but not limited to, prescribing practitioners, non-party pharmacies and pharmacists, individuals and entities involved in diversion and distribution of prescription opioids, individuals and entities involved in distribution and sale of illegal opioids, individuals involved in procuring diverted prescription opioids and/or illegal drugs, delivery services, federal, state, and local government entities, and health insurers and pharmacy benefit managers. 23 Okla. Stat. § 23-15.

56. The damages which Plaintiff may be entitled to recover if liability is established (which liability is specifically denied) are limited to reasonable damages, and exclude unconscionable and grossly oppressive damages contrary to substantial justice. See 23 Okla. Stat. § 97.

57. Plaintiff's claims against H. D. Smith are barred to the extent they rely, explicitly or implicitly, on a theory of market-share liability.

58. Plaintiff's claims are barred, in whole or in part, from recovering costs incurred in providing public services by the free-public-services and/or municipal-cost-recovery doctrines.

59. The claims asserted in the FAC are barred, in whole or in part, because federal agencies have exclusive or primary jurisdiction over the matters asserted in the FAC.

60. Some or all of Plaintiff's claims are preempted by federal law, including (without limitation) the federal Controlled Substances Act and the Food, Drug, and Cosmetic Act ("FDCA").

61. The conduct of H. D. Smith conformed with the FDCA and the requirements of the FDA, and the activities of H. D. Smith alleged in the FAC conformed with all state and federal statutes, regulations, and industry standards based on the state of knowledge at the relevant time(s) alleged in the FAC.

62. Plaintiff's claims are barred, in whole or in part, by conflict preemption as set forth in the United States Supreme Court's decisions in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) and *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013).

63. Plaintiff's claims are preempted insofar as they conflict with Congress' purposes and objectives in enacting relevant federal legislation and authorizing regulations, including the Hatch-Waxman Amendments to the FDCA and implementing regulations. *See Geier v. Am. Honda Co.*, 529 U.S. 861 (2000).

64. To the extent Plaintiff asserts claims that depend solely on violations of federal law, including any claims of a "fraud on the FDA" with respect to the Marketing Manufacturer Defendants' disclosure of information related to the safety of their medications at issue and/or

each of the Defendants' compliance with the statutes or regulations administered and/or enforced by the DEA, such claims are barred and should be dismissed. *See Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).

65. Plaintiff's claims are barred, in whole or in part, by the deference that common law accords discretionary actions by the FDA under the FDCA and discretionary actions by the DEA under the Controlled Substances Act.

66. If Plaintiff incurred the damages alleged, which is expressly denied, H. D. Smith is not liable for damages because the methods, standards, or techniques of designing, manufacturing, labeling, and distributing the prescription medications at issue complied with and were in conformity with the laws and regulations of the Controlled Substances Act, the FDCA, and the generally recognized state of the art in the industry at the time the product was designed, manufactured, labeled, and distributed.

67. Plaintiff's claims are barred to the extent they are based on any allegations involving failure to provide adequate warnings or information because all warnings or information that accompanied the allegedly distributed products were approved by the United States Food & Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301, *et seq.*), as amended, or Section 351, Public Health Service Act (42 U.S.C. § 262), as amended, or the warnings and information provided were those stated in monographs developed by the United States Food & Drug Administration for pharmaceutical products that may be distributed without an approved new drug application.

68. To the extent that Plaintiff relies on letters or other informal guidance from the DEA to establish H. D. Smith's regulatory duties, such informal guidance cannot enlarge H. D.

Smith's regulatory duties in the absence of compliance by DEA with the requirements by the Administrative Procedure Act, 5 U.S.C. § 551, *et seq.*

69. Plaintiff's claims are barred to the extent they are based on alleged violations of industry customs because purported industry customs do not create legal duties on H. D. Smith.

70. The claims asserted in the FAC are barred, in whole or in part, by the Restatement (Second) of Torts § 402A, Comments j and k, and Restatement (Third) of Torts: Products Liability § 6.

71. Plaintiff's claim of public nuisance is barred or limited because no action of H. D. Smith involved interference with real property; illegal conduct perpetrated by third parties involving the use of an otherwise legal product does not involve a public right against the distributor sufficient to state a claim for public nuisance; the alleged public nuisance would have impermissible extraterritorial reach; and the alleged conduct of H. D. Smith is too remote from the alleged injury as a matter of law and due process.

72. Plaintiff's claims are barred, reduced, and/or limited pursuant to the applicable Oklahoma statutory and common law regarding limitations of awards, caps on recovery, and setoffs.

73. To the extent that Plaintiff claims relate to H. D. Smith's alleged advertising, public statements, lobbying, or other activities protected by the First Amendment to the Constitution of the United States or by the Constitution of the State of Oklahoma or that of any other state whose laws may apply, such claims are barred.

74. H. D. Smith is immunized for claims relating to H. D. Smith's involvement with third party industry associations and or other organizations that are separate from H. D. Smith under the *Noerr-Pennington* Doctrine.

75. Plaintiff's damages, if any, were the direct result of pre-existing medical conditions, idiosyncratic reaction to medications on the part of the medication users and/or as a result of circumstances over which H. D. Smith had and continue to have no control.

76. Plaintiff's claims or damages are barred because users of the medications at issue used them after they knew, or should have known, of their alleged risks.

77. Plaintiff fails to plead any actionable misrepresentation or omission made by or attributable to H. D. Smith.

78. To the extent that Plaintiff is alleging fraud, fraudulent concealment, or similar conduct, Plaintiff has failed to plead fraud with sufficient particularity.

79. Plaintiff's public-nuisance claim is barred or limited to the extent that Plaintiff lacks the statutory authority to bring a nuisance claim under Oklahoma law or their own applicable laws, codes or regulations.

80. Plaintiff's RICO claims are barred, in whole or in part, by the absence of the existence of an "enterprise" for the purposes of RICO liability.

81. Plaintiff's RICO claims are barred, in whole or in part, by the absence of an "association" between H. D. Smith and any other defendant or entity alleged to be part of an "enterprise" for purposes of RICO.

82. Plaintiff's RICO claims are barred, in whole or in part, because H. D. Smith did not participate in any "enterprise."

83. Plaintiff's RICO claims are barred, in whole or in part, because H. D. Smith did not engage in a pattern of racketeering activity under RICO.

84. Plaintiff's RICO claims are barred, in whole or in part, because H. D. Smith did not knowingly agree to facilitate any schemes that include the operation or management of a RICO enterprise.

85. Plaintiff's claims are barred, in whole or in part, by the absence of a conspiracy, including a lack of agreement to commit any unlawful predicate acts, necessary to establish a valid RICO claim under 18 U.S.C. § 1962(d).

86. Plaintiff's RICO claims are barred, in whole or in part, because H. D. Smith did not commit any predicate acts that may give rise to liability under 18 U.S.C. § 1962.

87. Plaintiff's RICO claims are barred, in whole or in part, because there are no allegations that H. D. Smith adopted the goal of furthering or facilitating any criminal endeavor as necessary to support Plaintiff's civil conspiracy theory of liability.

88. Plaintiff's alleged damages do not constitute injury to business or property interests cognizable under RICO.

89. Plaintiff's RICO claims are barred, in whole or in part, because the alleged predicated acts—namely, failure to report and halt suspicious orders under the Controlled Substances Act, do not qualify as racketeering activity for purposes of RICO.

90. Plaintiff's claims are barred, in whole or in part, because neither the users of the subject prescription medications nor their prescribers relied to their detriment upon any statement made by H. D. Smith in determining to use or prescribe the subject prescription medications.

91. H. D. Smith is not liable for any statements in any Manufacturer's branded or unbranded materials.

92. Plaintiff's claims are barred to the extent that the subject prescription medications were misused, modified, altered, or changed from the condition in which they were sold, which

misuse, modification, alteration, or change caused or contributed to cause Plaintiffs' alleged injuries or damages.

93. H. D. Smith is entitled to, and claims the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute of this State or any other state whose substantive law might control the action.

94. H. D. Smith adopts by reference any additional applicable defense pled by any other defendants not otherwise pled herein. H. D. Smith hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during or as a result of the discovery proceedings in this action and hereby reserves its right to amend its answer to assert such defense.

95. H. D. Smith adopts by reference all defenses asserted in any party's motion to dismiss filed herein.

96. H. D. Smith asserts all applicable defenses under Federal Rules of Civil Procedure 8(c) and 12(b) and/or Oklahoma Rules of Civil Procedure § 2012 as investigation and discovery proceeds.

97. H. D. Smith reserves the right to add any other defense available under the Oklahoma Code, Oklahoma common law, and/or Oklahoma Constitution.

PRAYER FOR RELIEF

H. D. Smith, LLC prays that: (1) Plaintiff take nothing by reason of the FAC; (2) H. D. Smith, LLC recover its costs and attorneys' fees incurred herein; and (3) for all other such relief as the Court deems proper.

JURY DEMAND

H. D. Smith, LLC respectfully requests a jury in the maximum number allowed by law at the time of the trial of this matter on any disputed issue of material fact.

DATED: July 26, 2019

Respectfully submitted,

/s/ William E. Padgett

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CERTIFICATE OF SERVICE

I, William E. Padgett, certify that the foregoing document was served on July 26, 2019, via the Court's ECF system to all counsel of record.

/s/ William E. Padgett

William E. Padgett